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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,315

04/08/2008

Lawrence Solomon

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EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

01/20/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,315	Applicant(s) SOLOMON ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-12 and 15-33 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-12,15-26 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/27/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 12/17/2010 are acknowledged.
2. Claims 2, 4-6, and 13-14 were cancelled. Claims 27-32 were withdrawn.
3. Claims 1, 3, 7-12, 15-26 and 33 are included in the prosecution.

Amendment

4. Claim 1 was amended. However, please note that claim 1 has the incorrect status identifier. Claim 1 was identified as "previously presented" instead of "Currently Amended". Appropriate correction is required.

Information Disclosure Statement

5. The information disclosure statement (IDS) filed on 09/27/2010 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

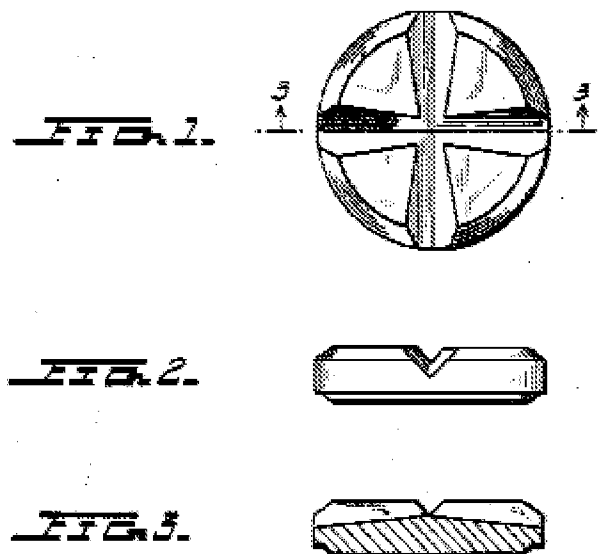
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 3, 7-12, 15-17, 21-26 and 33 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447).

The claimed invention is a pharmaceutical tablet comprising one or more layers forming a first inactive segment containing either an undetectable amount of drug or a pharmacologically ineffective amount of drug, one face of which is contiguous with an active layer containing a drug or drugs, said active layer being divided to form substantially identical first and second unitary segments each having a top and bottom face and only one of the faces contacting the first inactive segment. The first inactive segment has a score positioned between, and the surface contiguous with, the first and the second unitary segments.

Langauer teaches a tablet having a breaker score assuring accurate and easy breakage into predetermined portions (Abstract). Fig. 1 is a top view of the tablet, Fig. 2 is a right side view and Fig. 3 is a cross-sectional view taken on line 3-3 of Fig. 1.



Langauer teaches a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface (Col. 4, claim 1, lines 6-23). Langauer also teaches that “the sectioning of scored tablets is designed so that the active substance contained in each tablet (medicaments, active pharmacological agents) can be administered fully or to the extent of half or a quarter, depending on prescription or requirement” (Col. 1, lines 26-30). Langauer teaches variations in weight and in content of the active substances in the separated portions of scored tablets (Col. 1, lines 38-51).

Langauer does not expressly teach a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug.

Ting teaches a multiplex drug delivery system suitable for oral administration containing at least two distinct drug dosage packages and substantially enveloped by a **scored film coating** that allows the separation of the multiplex drug delivery system into individual drug dosage packages (emphasis added, Abstract, Page 2, lines 18-34, Page 3, line 17 to Page 4, line 12, Page 6, lines 5-14, claims 1-37). The scored film coating reads on the inactive segment. Fig. 1 shows an oblong tablet scored in the middle to allow for easy breaking of the tablet (Page 6, lines 13-14).

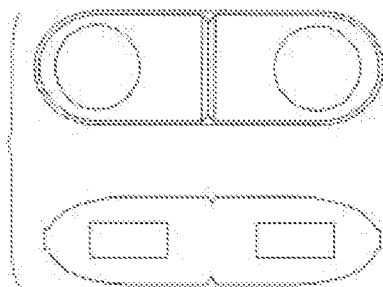


FIG. 1

The extended release compartment can comprise a combination of a hydrophilic and a hydrophobic material (Page 2, lines 18-34) and is scored (Page 6, lines 5-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment (i.e., an inactive segment), as taught by Ting, and produce the instant invention.

One of ordinary skill in the art would combine the tablets of Langauer and Ting because it is obvious to use a known technique (scoring tablets in order to assure accurate and easy breakage into predetermined portions – as taught by Langauer) to improve similar products (such as the tablets with a scored extended release compartment or an inactive segment– as taught by Ting). Please see MPEP 2141.

Applicant has not established that the art does not have an ineffective or an undetectable amount of drug. Applicant has not identified any ranges/amounts deemed to be ineffective or undetectable. Furthermore, claim 1, as currently amended does not exclude the substantial enveloping by “a scored film coating” as taught by Ting. The scored film coating reads on the inactive segment claimed by Applicant. Instant claims do not recite any proportion or quantity of the inactive segment to distinguish from the substantial enveloping by “a scored film coating” as taught by Ting. Instant claims permit the presence of a substantial enveloping by “a scored film coating”.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 1, 3, and 7-9, the pharmaceutical tablet comprising a first segment one face of which is contiguous with substantially identical first and second unitary segments that contain a drug or drugs would have been obvious over the tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer (Col. 4, claim 1, lines 6-23) in view of the tablet containing a scored film coating and extended release compartment that envelopes the immediate release compartments (Abstract, Page 2, lines 18-34, Page 6, lines 5-14, claims 1-37, Fig. 1). Regarding the limitation of a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug and the limitations of claims 7-9 would have been obvious over the scored film coating and extended release compartment that envelopes the immediate release compartments, as taught by Ting (Abstract, Page 2, lines 18-34, Page 6, lines 5-14, claims 1-37, Fig. 1). Since Ting teaches that the extended release compartment can comprise a combination of a hydrophilic and a hydrophobic material and does not require the inclusion of a drug in an embodiment of the extended release compartment, this reference renders obvious the limitation of a segment containing either an

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undetectable amount of a drug or a pharmacologically ineffective amount of drug (Page 2, lines 18-32).

Regarding instant claim 3, the one or more additional unitary segments in addition to the first and second unitary segments that are optionally present and are derived from the same layer or layers as said first unitary segment would have been obvious over the two or more discrete segments of the divisible tablet, as taught by Langauer (Fig. 2) in view of the multiplex drug delivery system containing at least two distinct drug dosage packages taught by Ting (Fig. 1).

Regarding instant claim 10, the limitation of the first segment that is derived from a granulation that does not contain a drug would have been obvious over the granulation (Page 5, lines 27-30) in view of the extended release compartment that may not contain a drug (Page 2, lines 18-32) as taught by Ting.

Regarding instant claim 11, the limitation of additional unitary segments that are contained in the tablet which are compositionally different from the composition of said first unitary segment and said second unitary segment and are derived from a granulation containing a drug would have been obvious over the variations in content of the active substance as taught by Langauer (Col. 1, lines 38-42).

Regarding instant claim 12, the limitation of the first unitary and the second unitary segments that are outer segments would have been obvious over the divisible tablets illustrated by Figures 1-3 by Langauer.

Regarding instant claim 15, the limitation of a substantially vertical score in said first segment, said score being vertically aligned with the center of the space between

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said first unitary segment and said second unitary segment would have been obvious over the divisible tablet taught by Langauer (Figures 1-3).

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the two or more discrete segments of the divisible tablet taught by Langauer (Figure 1). One of ordinary skill in the art would find it obvious to include additional segments based on the desired fractions or doses of the whole tablet.

Regarding instant claims 17 and 33, the limitation of the drugs would have been obvious over the drugs including non-steroid anti-inflammatory drugs (used for the treatment of pain) taught by Ting (Page 3, line 17 to Page 4, line 12).

Regarding instant claims 21-22, the limitation of the first segment adjoining a plurality of unitary segments on the side of said first segment that is opposite the surface adjoining said first and second unitary segments would have been obvious over the divisible tablet, as illustrated in Figure 1 by Langauer.

Regarding instant claims 23-26, the methods of breaking a pharmaceutical tablet would have been obvious over the tablet that may be divided into discrete segments and administered, as taught by Langauer (Abstract and Figures 1-3).

Response to Arguments

8. Applicant's arguments, see Page 6, filed 12/17/2010, with respect to the rejection of claims 1, 3, 7-12, 15-17, 21-26 and 33 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) have been fully considered but are not persuasive.

Applicant argues that "... combining Langauer and Ting would only provide scored tablets of Langauer (as the active portions) enveloped by a scored extended release composition (the inactive portion). However, the subject invention is different than this "combination" resulting from Langauer and Ting." Applicant argues that "the active portions of a Langauer/Ting combination tablet are not formed from a "divided" layer; rather, the active portions of a Langauer/Ting tablet are discrete tablets formed individually prior to being "coated" or "substantially enveloped" by (i.e., posited within) the inactive composition." Applicant argues that "the active unitary segments of the claimed invention have only one face which is in contact with the inactive layer or segment. In contradistinction, the active portions of a Langauer/Ting combination necessarily have more than one face in contact with the inactive portion since they are "substantially enveloped" by the inactive composition. Ting describes envelopment of the active portions by "press coating" the active portions with the inactive composition. By having only one face of the active segments in contact with the inactive layer, the subject tablets do not have any active portion "substantially enveloped" by the inactive composition."

This is not persuasive because although Ting teaches that the extended release compartment can comprise a combination of a hydrophilic and a hydrophobic material and does not require the inclusion of a drug in an embodiment of the extended release compartment, this reference renders obvious the limitation of a segment containing either an undetectable amount of a drug or a pharmacologically ineffective amount of drug (Page 2, lines 18-32) because Ting also discloses embodiments where an active can be included in the extended release compartment (Page 12, claim 2 and Page 10,

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Table 1). Instant claim 1 does not recite any ranges/amounts deemed to be ineffective or undetectable with respect to the amount of active. Therefore, the extended release compartment of Ting reads on the inactive segment, and the embodiment of Ting in which the extended release compartment contains an amount of drug reads on the active segment that may be divided.

Furthermore, claim 1, as currently amended does not exclude the substantial enveloping by “a scored film coating” and the extended release compartment as taught by Ting. Instant claims do not recite any proportion or quantity of the inactive segment to distinguish from the substantial enveloping by “a scored film coating” as taught by Ting. Instant claims permit the presence of a substantial enveloping by “a scored film coating”.

Applicant argues that: “Advantageously, the subject tablets can be formed using a conventional bi-layer tablet press and can provide the unexpected result of forming three or more segments from only two layers (one layer forming the inactive segment and one divided layer forming two active segments.) This is not achieved by Langauer or Ting individually or combined, since forming the two active portions each require a compression step, and the inactive “envelope” requires a third compression step.”

Applicant argues that: “Not only would a Langauer/Ting combination tablet require three compression steps, as discussed above, but the press-coating envelopment step can further require specialized press-coating machinery or tooling. Such required machinery or tooling can be avoided by the conventional layered tablet press process employed in the manufacture of the subject invention.”

This is not persuasive because Applicant's argument is directed toward the formation or process of producing the tablet, whereas the claims are directed to a product and process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. The unexpected results argued by Applicant would be expected from the divisible, scored tablets taught by Langauer and Ting.

Applicant argues that: "Neither Langauer nor Ting et al. references teach or suggest a readily divisible tablet which has an inactive layer/segment which contacts only one face of each active layer/segment. Further, there is no motivation provided in the prior art to modify the dosage forms described in Langauer or Ting et al. which would lead a person of ordinary skill in the art to the unique and unobvious tablets of the claimed invention."

This is not persuasive because the limitations of instant claims are rendered obvious by the divisible, scored tablets taught by Langauer and Ting, particularly the scored film coating (that reads on the inactive segment) and an embodiment of the extended release compartment that contains an amount of active and that is also scored and may be divided, as taught by Ting. One of ordinary skill in the art would find it obvious to modify the dosage forms taught by the prior art references because the addition of active in the scored film coating or in the extended release compartment and the amount of active (if it is included) are modifiable options, and are disclosed by Ting.

Therefore, the rejection of 09/30/2010 is maintained.

Claim Rejections - 35 USC § 103

9. Claims 17-18 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Addicks et al. (US 5,041,430).

Langauer and Ting are discussed above.

Langauer and Ting do not expressly teach warfarin as the drug in the tablet.

Addicks teaches a multilayer tablet that comprises warfarin (Col. 7, line 46 to Col. 8, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises warfarin, as taught by Addicks, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17-18, the limitation of warfarin would have been obvious over the warfarin in the multilayer tablet taught by Addicks (Col. 7, line 46 to Col. 8, line 9).

Response to Arguments

10. Applicant's arguments, see Page 8, filed 12/17/2010, with respect to the rejection of claims 17-18 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Addicks et al. (US 5,041,430) have been fully considered but are not persuasive.

Applicant argues that "... irrespective of the use of warfarin, the Addicks reference does not cure the defects of Langauer or Ting, taken separately or combined. Addicks does not teach or describe a tablet configured as claimed - namely, a tablet comprising a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment - i.e., the active is not enveloped by the inactive." Applicant argues that: "Combining Addicks with the Langauer and/or Ting references would only provide a teaching of two warfarin-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Addicks reference with Langauer and/or Ting, et al., is not the claimed invention."

This is not persuasive because the structure and arrangement of the tablet, the segments and the scoring are rendered obvious by the teachings of Langauer and Ting, as discussed above. The deficiency in the Langauer Ting combination is regarding warfarin, and this deficiency is remedied by Addicks. The references are properly combined because one of ordinary skill in the art would find it obvious to use various drugs in the tablet formulation, including the drug warfarin, as disclosed in the multilayer tablet of Addicks.

Therefore, the rejection of 09/30/2010 is maintained.

Claim Rejections - 35 USC § 103

11. Claims 17 and 19 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Eberlin et al. (US 3,696,091).

Langauer and Ting are discussed above.

Langauer and Ting do not expressly teach digoxin as the drug in the tablet.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17 and 19, the limitation of digoxin would have been obvious over the digoxin in the tablet taught by Eberlin (Col. 12, lines 20-45).

Response to Arguments

12. Applicant's arguments, see Page 9, filed 12/17/2010, with respect to the rejection of claims 17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Eberlin et al. (US 3,696,091) have been fully considered but are not persuasive.

Applicant argues that "... irrespective of the use of digoxin, the Eberlin reference does not cure the defects of Langauer or Ting. Eberlin does not teach or describe a tablet configured as claimed - namely, a tablet having a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment - i.e., the active is not "substantially enveloped" by the inactive." Applicant argues that: "Combining Eberlin with the Langauer and/or Ting references would only provide a teaching of two digoxin-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Eberlin reference with Langauer and/or Ting, et al., is not the claimed invention."

This is not persuasive because the structure and arrangement of the tablet, the segments and the scoring are rendered obvious by the teachings of Langauer and Ting, as discussed above. The deficiency in the Langauer Ting combination is regarding digoxin, and this deficiency is remedied by Eberlin. The references are properly combined because one of ordinary skill in the art would find it obvious to use various drugs in the tablet formulation, including the drug digoxin, as disclosed in the tablet of Eberlin.

Therefore, the rejection of 09/30/2010 is maintained.

Claim Rejections - 35 USC § 103

13. Claims 17 and 20 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Franz et al. (US 6,555,581 B1).

Langauer and Ting are discussed above.

Langauer and Ting do not expressly teach levothyroxine as the drug in the tablet.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, , combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17 and 20, the limitation of levothyroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

Response to Arguments

14. Applicant's arguments, see Page 10, filed 12/17/2010, with respect to the rejection of claims 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Franz et al. (US 6,555,581 B1) have been fully considered but are not persuasive.

Applicant argues that "... irrespective of the use of levothyroxine, the Franz reference does not cure the defects of Langauer or Ting. Franz does not teach or describe a tablet having a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment - i.e., the active is not "substantially enveloped" by the inactive." Applicant argues that: "Combining Franz with the Langauer and/or Ting references would only provide a teaching of two levothyroxine-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Franz reference with Langauer and/or Ting, et al., is not the claimed invention."

This is not persuasive because the structure and arrangement of the tablet, the segments and the scoring are rendered obvious by the teachings of Langauer and Ting, as discussed above. The deficiency in the Langauer Ting combination is regarding levothyroxine, and this deficiency is remedied by Franz. The references are properly combined because one of ordinary skill in the art would find it obvious to use various drugs in the tablet formulation, including the drug levothyroxine, as disclosed in the tablet of Franz.

Therefore, the rejection of 09/30/2010 is maintained.

Response to Arguments for

Double Patenting Rejections/Terminal Disclaimers

15. Applicant's arguments, see Page 10, filed 12/17/2010, with respect to the following obviousness-type double patenting rejections have been fully considered.

- Rejection of claims 1, 3, 7-12, 15-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14 and 17 of copending Application No. 11/441,455 (the '455 Application)
- Rejection of claims 1, 3, 7-12, 15-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-15 and 20 of U.S. Patent No. 7,329,418 (the '418 patent)
- Rejection of claims 1, 3, 7-12, 15-26 and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 6-11 of U.S. Patent No. 7,318,935 (the '935 patent)

Applicant filed terminal disclaimers over copending Application No. 11/441,455, U.S. Patent No. 7,329,418, and U.S. Patent No. 7,318,935 on 09/07/2010. Since these terminal disclaimers were approved, the obviousness-type double patenting rejections have been withdrawn.

Conclusion

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615